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Omni Cardio 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: k122291

Company / Contact Person

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Date Prepared

August 29, 2012

Regulatory Declarations

Common / Usual Name	MAS® Omni•CARDIO
Trade / Proprietary Name	Thermo Scientific MAS® Omni•CARDIO
Classification Regulation	21 CFR 862.1660
Device Class	Class I, Reserved
Device Regulation Panel	Clinical Chemistry
Product Code	JJY

Intended Use

MAS® Omni•CARDIO

Thermo Scientific MAS® Omni•CARDIO™ is intended for use in the clinical laboratory as an assayed control serum for monitoring assay conditions related to cardiac and associated critical marker determinations.

Legally Marketed Device to Which Equivalency is Claimed

The Thermo Scientific MAS® Omni•CARDIO is substantially equivalent to the previously cleared MAS® CardioImmune TL (K040880) and MAS® CardioImmune XL (K061196).

Device Description

Each MAS® Omni•CARDIO control kit is packaged in a plastic clamshell container with a product insert and value sheet. Each vial contains 3 mL of the control level in an amber glass bottle with black sterile caps. Kits are stored frozen at -20°C.

Below are the different kit configurations:

Kit	Configuration
Level UL	6 x 3 mL
Level L	6 x 3 mL
Level 1	6 x 3 mL
Level 2	6 x 3 mL
Level 3	6 x 3 mL
Multi-Pack	Level 1 – 2 x 3 mL Level 2 – 2 x 3 mL Level 3 – 2 x 3 mL
Sample Pack	Level UL – 1 x 3 mL Level L – 1 x 3 mL Level 1 – 1 x 3 mL Level 2 – 1 x 3 mL Level 3 – 1 x 3 mL

MAS® Omni•CARDIO control levels are provided in liquid form and are to be stored at -20°C until the expiration date on the label. The control levels are prepared from human serum and contain the following constituents: Beta-Human Chorionic Gonadotropin (ß-HCG), B-Type Natriuretic Peptide (BNP), Creatine Kinase-MB (CK-MB), D-Dimer, Digitoxin, Homocysteine, High Sensitivity C-Reactive Protein (hsCRP), Human Chorionic Gonadotropin (HCG), Myeloperoxidase (MPO), Myoglobin, N-Terminal Prohormone of Brain Natriuretic Peptide (NT-proBNP), Procalcitonin (PCT), Total Creatine Kinase (CK), Troponin I, Troponin T.

Stability Testing and Value Assignment Summary:

Accelerated testing was carried out for the evaluation lots at three elevated temperatures in order to support a shelf life storage temperature of -20°C for 36 months. For each temperature tested, the required number of days of stress without failure was determined that would be equivalent to 36 months storage at -20°C. All analytes and lots tested met the minimum number of days for all temperatures tested in support of a shelf life claim of 36 months frozen at -20°C. Real time testing at -20°C is on-going.

Open and closed vial testing was carried out at 5°C for all claimed analytes on the evaluation lots. Vials were thawed, mixed, and placed at 2-8°C for the study. Vials were opened briefly each work day (open vial) or remained unopened (closed vial) until time of assay. Multiple timepoints were tested and the point of failure determined by linear regression analysis of the data. All analytes met the required claim of 15 days storage for both open and closed vial testing with the exception of Myoglobin and NT-ProBNP (10 days) and Homocysteine (5 days).

Value assignment testing was carried out to determine typical values that would be seen for the product across different analyzer platforms. Evaluation lots were sent to multiple sites, typically 2 or 3 lots per instrument platform, and assayed over 5 days in duplicate. For each analyte and analyzer combination, the data was averaged to determine a grand mean. Value assignment ranges were established at +/-20% around the grand mean and were expanded if needed to

ensure the minimum and maximum values in the data set were within the established range. Values for the evaluation lots all fell within the established ranges.

Omni Cardio – Target Ranges

Analyte	Units	Level UL		Level L		Level 1		Level 2		Level 3	
BNP 32	pg/mL	56	104	56	104	104	216	360	640	1400	2600
CK-MB	ng/mL	1.7	4.3	1.7	4.3	3.5	6.5	17.5	32.5	60	100
D-Dimer	ng/mL	Not Claimed		Not Claimed		190	400	700	1300	2100	3900
Digitoxin	ng/mL	3.9	8.1	3.9	8.1	8.5	13.5	15.0	29.0	33	62
Homocysteine	µmol/L	Not Claimed		Not Claimed		2.5	6.5	5.0	12.0	13.0	31.0
hsCRP	mg/L	0.20	0.80	0.20	0.80	1.30	3.20	3.5	6.5	7.0	13.0
Myeloperoxidase (MPO)	pmol/L	20	46	20	46	170	330	560	1040	2450	4550
Myoglobin	ng/mL	11.0	29.0	11.0	29.0	31	57	160	310	450	750
NT-proBNP	pg/mL	45	125	45	125	285	620	1600	3100	8400	15600
Procalcitonin	ng/mL	0.18	0.32	0.18	0.32	0.35	0.65	1.90	3.90	7.2	15.6
β-HCG	mIU/mL	Not Claimed		Not Claimed		6.0	12.0	18	35	150	270
Total CK	IU/L	42	78	42	78	91	169	200	400	420	780
Troponin I (TnI)	ng/mL	0.025	0.080	0.100	0.280	0.20	0.45	0.75	1.50	10.0	20.0
Troponin T (TnT)	pg/mL	10	30	35	65	100	200	450	750	4800	7800

Comparison of Technological Characteristics

Comparison	Proposed Device	Predicate1	Predicate 2
Proprietary Name	Thermo Scientific MAS® Omni•CARDIO	MAS® CardioImmune TL	MAS® CardioImmune XL
510k Number	k122291	k040880	k061196
Intended Use	Thermo Scientific MAS® Omni•CARDIO™ is intended for use in the clinical laboratory as an assayed control serum for monitoring assay conditions related to cardiac and associated critical marker determinations.	CardioImmune® TL is intended for use in the clinical laboratory as an assayed control serum suitable for monitoring assay conditions in specific cardiac marker determinations.	MAS® CardioImmune® XL is intended for use in the clinical laboratory as an assayed control serum for monitoring assay conditions in specific cardiac marker determinations.
Matrix	Human Serum	Human Serum	Human Serum
Format	Frozen Liquid	Frozen Liquid	Frozen Liquid
Control Levels	5	4	4
Storage	-20°C	-20°C	-20°C
Shelf Life	36 months	36 months	36 months
Open Vial Stability	15 days (2-8°C) except NT-ProBNP, Myoglobin (10 days) Homocysteine (5 days)	30 days (2-8°C) except NT-ProBNP (10 days)	30 days (2-8°C) except CK-MB, Troponin-T, BNP 32, NT-ProBNP (15 days) Myoglobin (5 days)
Closed Vial Stability	15 days (2-8°C) except ProBNP, Myoglobin (10 days) Homocysteine (5 days)	30 days (2-8°C)	N/A
Analytes	BNP 32 CK-MB D-Dimer Digitoxin Homocysteine hsCRP Myeloperoxidase (MPO) Myoglobin NT-ProBNP Procalcitonin (PCT) bHCG Total CK Troponin-I (TnI) Troponin-T (TnT)	CK-MB Digitoxin hsCRP Myoglobin NT-ProBNP Troponin-I (TnI) Troponin-T (TnT)	BNP 32 CK-MB Digitoxin Homocysteine hsCRP Myoglobin NT-ProBNP Troponin-I (TnI) Troponin-T (TnT)

Conclusion

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

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Silver Spring, MD 20993

Microgenics Corporation
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AUG 31 2012

Re: k122291
Trade Name: MAS® Omni·CARDIO
Regulation Number: 21 CFR §862.1660
Regulation Name: Quality Control Material (assayed and unassayed)
Regulatory Class: Class I, reserved
Product Codes: JJY
Dated: July 30, 2012
Received: July 31, 2012

Dear Ms. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known)
k122291

Device Name
MAS® Omni•CARDIO

Indications For Use
MAS® Omni•CARDIO
Thermo Scientific MAS® Omni•CARDIO™ is intended for use in the clinical laboratory as an assayed control serum for monitoring assay conditions related to cardiac and associated critical marker determinations.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K122291